MICROALBUMIN

OSR6167	**4 x 15 mL**	**R1**
	4 x 5 mL	**R2**

Intended Use
System reagent for the quantitative determination of Microalbumin (MALB) in human urine on Beckman Coulter AU analyzers.

Summary
Microalbuminuria is the term given to the condition of increased excretion of albumin in urine. High urinary Microalbumin is an early marker for renal disease. Measurement of Microalbumin levels in urine are used to predict the development of diabetic nephropathy, as this protein tends to appear ahead of other serum proteins in urine during the course of renal glomerular damage. Measurement of Microalbumin is therefore considered a standard for the detection of diabetic complications.[1,2]

Methodology
Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. Turbidimeters measure the reduction of incident light due to reflection, absorption, or scatter.

In the Beckman Coulter procedure, the measurement of the decrease in light transmitted (increase in absorbance) through particles suspended in solution as a result of complexes formed during the antigen-antibody reaction, is the basis of this assay.

System Information
For AU400/400^{e}/480, AU600/640/640^{e}/680 and AU2700/5400 Beckman Coulter Analyzers.

Reagents
Final concentration of reactive ingredients:

Tris buffer	95 mmol/L
Goat anti-human Albumin antiserum	
Also contains preservatives.	

Precautions
1. For *in vitro* diagnostic use.
2. Do not ingest. Harmful if swallowed.
3. Contains sodium azide as a preservative which may react with lead joints in copper plumbing to form explosive compounds. Even though the reagent contains minute quantities of sodium azide, drains should be well flushed with water when discarding the reagent.

Preparation of reagents
The Microalbumin reagent is ready for use. No preparation is required.

Storage and stability
1. The unopened reagents are stable until the expiration date printed on the label when stored at 2 – 8°C.
2. Opened bottles of reagent are stable for 90 days when stored in the refrigerated compartment of the analyzer.

Indications of Deterioration
Visible signs of microbial growth, turbidity, precipitate or change in color in the Microalbumin reagents may indicate degradation and warrant discontinuation of use.

Specimen Collection And Preparation
Urine is the recommended specimen. The specimen should be a fresh or a 24 hour urine.[2]

Sample Storage and Stability
Urine specimens should be stored refrigerated (2 – 8°C) and can be used within one week or should be stored frozen at –20°C for up to one year.

Interfering Substances
Results of studies conducted[3] show that the following substances may interfere with this Microalbumin procedure:

The criteria for no significant interference is recovery within 10% of the initial value

Ascorbate:	No significant interference up to 20 mg/dL Ascorbate
Creatinine:	No significant interference up to 300 mg/dL Creatinine
Glucose:	No significant interference up to 3000 mg/dL Glucose

The information presented is based on results from Beckman Coulter studies and is current at the date of publication. Beckman Coulter Inc. makes no representation about the completeness or accuracy of results generated by future studies. For further information on interfering substances, refer to Young[4] for a compilation of reported interferences with this test.

Procedure
A complete list of test parameters and operational procedure can be found in the User's Guide appropriate to the analyzer.

Microalbumin

Materials Provided
Microalbumin Reagent

Materials required but not provided
Microalbumin Calibrator (ODR3024)
0.9% Saline

Stability of Final Reaction Mixture
The Beckman Coulter AU analyzers automatically compute every determination at the same time interval.

Calibration
The frequency of calibration for the Microalbumin turbidimetric procedure is every 90 days. Calibration of this Microalbumin procedure is accomplished by use of 0.9% saline and the Microalbumin Calibrator (Cat # ODR3024), which is traceable to a primary Albumin standard.

Recalibration of this test is required when any of these conditions exist:
1. A reagent lot number has changed or there is an observed shift in control values.
2. Major preventative maintenance was performed on the analyzer.
3. A critical part was replaced.

Quality Control
During operation of the Beckman Coulter AU analyzer at least two levels of an appropriate quality control material of human origin only, should be tested a minimum of once a day. In addition, these controls should be performed after calibration, with each new lot of reagent, and after specific maintenance or troubleshooting steps described in the appropriate User's Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.
Please note that recovery of non-Beckman Coulter controls may vary with reagent lots of immunoassay products, due to the use of non-human materials in the controls.

Results
Automatically printed out for each sample in mg/dL at 37°C.

Limitations of the procedure
The result of Microalbumin urine sample may be elevated when it immediately follows a serum sample. In order to eliminate this effect, it is recommended to:
a) Calibrate Microalbumin separately to other serum calibrations.
b) Avoid freely alternating serum and urine racks.
c) When changing from serum to urine samples during routine operation, place a sample cup containing 2% AU detergent in the first position of the urine rack and requisition a test for this sample.

Dynamic Range
The Microalbumin turbidimetric procedure is linear from 0.5 - 30 mg/dL. Samples exceeding the upper limit of linearity should be diluted and repeated. The sample may be diluted, repeated and multiplied by the dilution factor automatically utilizing the AUTO REPEAT RUN. Urine samples should be initially screened by an alternative method for grossly abnormal total protein. Samples with extremely high levels of protein should not be assayed for Microalbumin.
Prozone or hook effect may occur with highly elevated Microalbumin samples (> 600 mg/dL).

Expected Values
Urine:[5]

	24-h collection (mg/24h)	Timed collection (µg /min)	Spot collection (µg /mg creatinine)
Normal	< 30	< 20	< 30
Microalbuminuria	30 – 299	20 – 199	30 – 299
Clinical albuminuria	≥ 300	≥ 200	≥ 300

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice.

Specific Performance Characteristics
The following data was obtained using the Microalbumin reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

Precision[7]
Estimates of precision, based on CLSI recommendations,[6] are consistent with typical performance. The within run precision is less than 5% CV and total precision is less than 10% CV. Assays of urine pools and control sera were performed and the data reduced following CLSI guidelines above.

N = 100	Within run		Total	
Mean, mg/dL	SD	CV%	SD	CV%
0.85	0.01	1.6	0.02	2.0
2.90	0.02	0.7	0.03	1.1
5.08	0.04	0.7	0.06	0.9

Method Comparison[7]
Patient samples were used to compare this Microalbumin Reagent. The table below demonstrates representative performance on AU analyzers.

Y Method	AU640
X Method	AU600
Slope	0.992
Intercept	-0.022
Correlation Coeff. (r)	0.999
No. of Samples (n)	157
Range (mg/dL)	0.5-30.6

References

1. Wild D(Ed.)., The Immunology Handbook 1994.
2. Tietz, N.W., Textbook of Clinical Chemistry Second Edition, Burtis E.A. and Ashwood, E.R. eds. W.B. Saunders Company, 1994.
3. CLSI/NCCLS, Interference Test in Clinical Chemistry, EP7-P, 1986.
4. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, 5th Edition 2000.
5. American Diabetes Association, Diabetic Nephropathy, Diabetes Care 25:(Suppl. 1):S85-S89.
6. CLSI/NCCLS Evaluation Protocol EP5-T2, 1992.
7. Data is on file for specific AU analyzers.

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